APR 3 0 2012

Premarket Notification [510(k)] Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is : K110530

Company: Horiba ABX SAS
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Contact Person: Caroline Ferrer (caroline.ferrer@horiba.com)

Date Prepared: 12th April, 2012

Device Names:
The following reagents, controls & calibrators are for use in conjunction with the ABX PENTRA 400 instrument, cleared to market under K052007.

REAGENTS :

Trade/Proprietary Name:	**ABX PENTRA Creatinine 120 CP**
Common or Usual Name:	Creatinine
Device Class	Class II
Classification Name:	§862.1225 : Creatinine Test System
Product Code:	CGX: alkaline picrate, colorimetry, creatinine

CALIBRATORS:

Trade/Proprietary Name:	**ABX PENTRA Multical** (K052007)
Common or Usual Name:	Multical
Device Class	Class II
Classification Name:	§862.1150 : Calibrator
Product Code:	JIX ; Calibrator, Multi-Analyte Mixture

CONTROLS :

Trade/Proprietary Name:	**ABX PENTRA N Control** (K052007)
Common or Usual Name:	N Control
Device Class	Class I
Classification Name:	§862.1660 : Quality control material (assayed)
Product Code:	JJY ; Multi-Analyte Controls, All Kinds (Assayed)

Trade/Proprietary Name:	**ABX PENTRA P Control** (K052007)
Common or Usual Name:	P Control
Device Class	Class I
Classification Name:	§862.1660 : Quality control material (assayed)
Product Code:	JJY ; Multi-Analyte Controls, All Kinds (assayed)

Trade/Proprietary Name:	**ABX PENTRA Urine Control L/H** (K070249)
Common or Usual Name:	Urine control
Device Class	Class I
Classification Name:	§862.1660 : Quality control material (assayed)
Product Code:	JJY ; Multi-Analyte Controls, All Kinds (Assayed)

Substantial Equivalence:

The data and information supplied in this submission demonstrates substantial equivalence to their respective predicate devices:

Submission device	Substantially equivalent Predicate device
ABX PENTRA Creatinine 120 CP	K934361
ABX PENTRA Multical	K052007
ABX PENTRA N Control	K052007
ABX PENTRA P Control	K052007
ABX PENTRA Urine Control L/H	K070249

Description:

All the reagent, controls and calibrator included in this submission are for use on the **ABX PENTRA 400** (K052007), which is a discrete photometric benchtop clinical chemistry analyzer.

The **ABX PENTRA Creatinine 120 CP** is an in vitro diagnostic assay for the quantitative in vitro determination of creatinine in human serum, plasma and urine based on a kinetic method using alkaline picrate (Jaffé method). It is composed of a bi-reagent cassette (R1= 27.5 mL ; R2= 8 mL). Reagents are chemical solutions with additives.

The **ABX PENTRA Multical** is a lyophilized human serum calibrator with chemical additives and materials of biological origin. The assigned values of the calibrator components are given in the enclosed annex, ensuring optimal calibration of the appropriate HORIBA ABX SAS methods on the ABX PENTRA 400 analyzer.
This calibrator is provided in ten vials of 3 ml.

The **ABX PENTRA N Control** and **ABX PENTRA P Control** are quality control products consisting of lyophilized human serum with chemical additives and materials of biological origin added as required to obtain given component levels. The assigned values of the control components are given in the enclosed annexes, ensuring control of the appropriate HORIBA ABX SAS methods on the ABX PENTRA 400 analyzer. Each control is provided in ten vials of 5 ml.

The **ABX PENTRA Urine Control L/H** is a two-level (Low and High) quality control consisting of liquid solutions prepared from human urine with chemical additives and materials of biological origin added as required to obtain given component levels. The assigned values of the control components are given in the enclosed annex, ensuring control of the appropriate HORIBA ABX SAS methods on the ABX PENTRA 400 analyzer. Each control level is provided in one vial of 10 ml.

Intended Use:

All reagents in this submission are intended for use on the **ABX PENTRA 400** for the quantitative in-vitro determination of Creatinine using human serum, plasma and/or urine.

The controls and calibrator are intended for use in association with the above reagent.

Discussion of Performance Data:

ABX PENTRA Creatinine 120 CP :	
Sample type	Serum, Plasma and Urine
Detection limit	Serum/Plasma : 0.074 mg/dl Urine : 1.40 mg/dl
Limit of Quantitation	Serum/Plasma : 0.22 mg/dl Urine : 2.90 mg/dl
Accuracy and Precision	Serum/Plasma CV Total < 4.72% Urine CV Total < 2.06%
Measuring range	Serum/Plasma : 0.22 mg/dl – 18.08 mg/dl Urine : 2.90 mg/dl – 282.50 mg/dl
Upper linearity limit	Serum/Plasma : 18.08 mg/dl, and with automatic post-dilution : 54.24 mg/dl Urine : 282.5 mg/dl, and with automatic post-dilution : 847.50 mg/dl
Correlation	Serum/Plasma (n=165) : Y = 0.99 x + 0.03 (mg/dl) with r^2 = 0.9984 Urine (n=117) : Y = 1.00 x – 0.60 (mg/dl) with r^2 = 0.9984
Calibration stability	Serum/Plasma : 3 days Urine : 3 days
Reagent stability	closed stability: 36 months at 2-8°C on-board stability : 19 days

CALIBRATOR

ABX PENTRA Multical:		
Analytes	Already cleared (K052007, K060205, K060318, K060325, K060854, K062180, K062737, K060434, K072115, K110137)	Included in this submission
Alkaline phosphatase	√	√
Alanine aminotransferase	√	√
Amylase	√	√
Aspartate aminotransferase	√	√
Creatine kinase	√	√
GGT	√	√
LDH	√	√
Lipase	√	√

ABX PENTRA Multical:		
Albumin	√	√
Direct Bilirubin	√	√
Total Bilirubin	√	√
Calcium	√	√
Cholesterol	√	√
Creatinine 120	√	√
New Creatinine 120		√
Enzymatic Creatinine CP	√	√
Glucose HK	√	√
Glucose PAP	√	√
Iron	√	√
Lactic acid	√	√
Magnesium	√	√
Phosphorus	√	√
Total Protein	√	√
Total Protein 100	√	√
Triglycerides	√	√
Urea / Blood Urea Nitrogen	√	√
Uric acid	√	√
Format	Lyophilized human serum with chemical additives and materials of biological origin	
Stability	Closed stability: 24 months at 2-8°C Open stability: Once opened, the calibrator components** are stable for : 8 hours at 15°C to 25°C 2 days at 2°C to 8°C 2 weeks at –25°C to –15°C **Exceptions Direct Bilirubin 3 hours at 15°C to 25°C 8 hours at 2°C to 8°C 2 weeks at –25°C to –15°C Total Bilirubin 6 hours at 15°C to 25°C 1 day at 2°C to 8°C 2 weeks at –25°C to –15°C	

.../...

CONTROLS

ABX PENTRA N Control:		
Analytes	Already cleared (K052007, K060205, K060318, K060325, K060854, K062180, K062737, K060434, K072115, K110137)	Included in this submission

ABX PENTRA N Control:		
Alkaline phosphatase	√	√
Alanine aminotransferase	√	√
Amylase	√	√
Aspartate aminotransferase	√	√
Creatine kinase	√	√
GGT	√	√
LDH	√	√
Lipase	√	√
Albumin	√	√
Direct Bilirubin	√	√
Total Bilirubin	√	√
Calcium	√	√
Chloride	√	√
Cholesterol	√	√
HDL	√	√
LDL	√	√
Creatinine 120	√	√
New Creatinine 120		√
Enzymatic Creatinine CP	√	√
Glucose HK	√	√
Glucose PAP	√	√
Iron	√	√
Lactic acid	√	√
Magnesium	√	√
Phosphorus	√	√
Potassium	√	√
Sodium	√	√
Total Protein	√	√
Total Protein 100	√	√
Triglycerides	√	√
Urea / Blood Urea Nitrogen	√	√
Uric acid	√	√

.../...

Format	Lyophilized human serum with chemical additives and materials of biological origin
Stability	Closed stability: 30 months at 2-8°C Open stability: Once opened, the control components** are stable for : 12 hours at 15°C to 25°C 5 days at 2°C to 8°C 1 month at –25°C to –15°C **Exceptions Direct Bilirubin 4 hours at 15°C to 25°C

ABX PENTRA N Control:	
	8 hours at 2°C to 8°C 2 weeks at –25°C to –15°C Total Bilirubin 8 hours at 15°C to 25°C 1 day at 2°C to 8°C 2 weeks at –25°C to –15°C

ABX PENTRA P Control:		
Analytes	Already cleared (K052007, K060205, K060318, K060325, K060854, K062180, K062737, K060434, K072115, K110137)	Included in this submission
Alkaline phosphatase	√	√
Alanine aminotransferase	√	√
Amylase	√	√
Aspartate aminotransferase	√	√
Creatine kinase	√	√
GGT	√	√
LDH	√	√
Lipase	√	√
Albumin	√	√
Direct Bilirubin	√	√
Total Bilirubin	√	√
Calcium	√	√
Chloride	√	√
Cholesterol	√	√
HDL	√	√
LDL	√	√
Creatinine 120	√	√
New Creatinine 120		√
Enzymatic Creatinine CP	√	√
Glucose HK	√	√
Glucose PAP	√	√
Iron	√	√
Lactic acid	√	√
Magnesium	√	√
Phosphorus	√	√
Potassium	√	√
Sodium	√	√
Total Protein	√	√
Total Protein 100	√	√
Triglycerides	√	√
Urea / Blood Urea Nitrogen	√	√
Uric acid	√	√
Format	Lyophilized human serum with chemical additives and materials of biological origin	
Stability	Closed stability: 30 months at 2-8°C Open stability: Once opened, the control components** are stable for : 12 hours at 15°C to 25°C 5 days at 2°C to 8°C	

ABX PENTRA P Control:	
	1 month at –25°C to –15°C .../... **Exceptions Direct Bilirubin 4 hours at 15°C to 25°C 8 hours at 2°C to 8°C 2 weeks at –25°C to –15°C Total Bilirubin 8 hours at 15°C to 25°C 1 day at 2°C to 8°C 2 weeks at –25°C to –15°C

ABX PENTRA Urine Control L/H:		
Analytes	Already cleared (K07249, K072115, K110137)	Included in this submission
Amylase	√	√
Calcium	√	√
Creatinine 120	√	√
New Creatinine 120		√
Enzymatic Creatinine CP	√	√
Phosphorus	√	√
Glucose	√	√
Urea / Blood Urea Nitrogen	√	√
Uric acid	√	√
Urinary proteins	√	√
Format	Liquid solution prepared from human urine with chemical additives and materials of biological origin	
Stability	Closed stability: 2 years at 2-8°C Open stability: 30 days at 2-8°C	

Conclusions for Performance Testing :
The performance testing data conclude that the safety and effectiveness of the devices are not compromised, and that they met all acceptance criteria, demonstrating that the devices are substantially equivalent to their respective predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Horiba ABX SAS
c/o Ms. Caroline Ferrer
Parc Euromédecine
Rue du Caducée – BP 7290
34184 Montpellier cedex 4
FRANCE

APR 30 2012

Re: k110530
Trade Name: ABX PENTRA Creatinine 120 CP on ABX PENTRA 400 Clinical Chemistry Analyzer; ABX PENTRA Multical, ABX PENTRA N Control, ABX PENTRA P Control, ABX PENTRA Urine Control L/H
Regulation Number: 21 CFR §862.1225
Regulation Name: Creatinine Test System
Regulatory Class: Class II
Product Codes: CGX, JIX, JJY
Dated: April 23, 2012
Received: April 25, 2012

Dear Ms. Ferrer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K110530

Device Name: ABX Pentra Creatinine 120 CP on ABX PENTRA 400 Clinical Chemistry Analyzer

Indications For Use:

ABX PENTRA Creatinine 120 CP reagent, with associated calibrator and controls, is a diagnostic reagent for quantitative in vitro determination of Creatinine in human serum, plasma and urine based on a kinetic method using alkaline picrate (Jaffé method). Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.

Prescription Use X And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K110530

Indication for Use

510(k) Number (if known): K110530

Device Name: ABX PENTRA Multical

Indication For Use:

The ABX PENTRA Multical is a calibrator for use in the calibration of quantitative Horiba Medical methods on Horiba Medical clinical chemistry analyzers.

Prescription Use _X_ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K110530

Indication for Use

510(k) Number (if known): k110530

Device Name: ABX PENTRA N Control

Indication For Use:

The ABX PENTRA N Control is for use in quality control by monitoring accuracy and precision.

Prescription Use _X_ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k110530

Indication for Use

510(k) Number (if known): K110530

Device Name: ABX PENTRA P Control

Indication For Use:

The ABX PENTRA P Control is for use in quality control by monitoring accuracy and precision.

Prescription Use X (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____ (21 CFR Part 801 Subpart C)

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Evaluation and Safety

510(k) K110530

Indication for Use

510(k) Number (if known): K110530

Device Name: ABX PENTRA Urine Control L/H

Indication For Use:

The ABX PENTRA Urine Control L/H is for use in quality control by monitoring accuracy and precision.

Prescription Use _X_ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ___. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

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510(k) K110530